

COMMENT TO NOSB FROM OMRI

From: Brian Baker, Emily Brown Rosen
 To: The National Organic Standards Board
 Subject: Guidelines for determining what processing technologies shall be
 Reviewed by the NOSB
 Date: March 15, 2002

OMRI supports the intent of the Guidelines set forth by the NOSB in general and offers the following suggestions to help processors, certifiers, and the public to better understand acceptable organic processing techniques. OMRI suggests that items 2, 3, and 4 be combined into a single guideline, with examples provided to clarify their meaning. OMRI suggests that item 5 be omitted, because this does not clarify any subject. The NOSB should remind the public and potential petitioners that the NOP Final Rule excludes certain items.

Guidelines for determining what processing technologies shall be require a petition to be reviewed by the NOSB:

- 1) Processes that are strictly mechanical, physical, or biological are allowed for processing of organic food products. Any process that does not cause a change in the food, other than by mechanical, physical, or biological means, and does not introduce nonagricultural substances, other than those allowed already listed in §205.605, would not need to be reviewed.

Examples include: centrifuging, grinding, rolling, filtration, gravimetric separation, drying, churning, pressing, vacuum extraction, heating, cooking, distilling, natural fermentation, and UV light treatment.

- 2) Processes that involve the use of non-organic ingredients, processing aids, primary additives, or secondary additives as defined by FDA are subject to the requirements established in 7 CFR 205.270, 7 CFR 205.301(f), 7 CFR 205.600, 7 CFR 205.605, and 7 CFR 205.606. Any substance used would need to be petitioned, reviewed, recommended, and added to the National List to be allowed for using in processing food or ingredients labeled as organic, even when such processing results only in incidental amounts of a given substance in the food.

Examples of non-organic, nonagricultural substances that must appear on the National List to be used in organic processing include: acids and bases used in hydrolysis; fermentation organisms and cultures; use of secondary additives such as ion-exchange resins and membranes; metals used as charged catalysts (e.g., nickel or platinum used to hydrogenate oils); gases that are added to food (e.g., hydrogen for hydrogenation or carbon dioxide for supercritical extraction); antifoaming agents; and volatile boiler water additives that carry over in steam.

- 3) The NOSB will not consider petitions to use ingredients or processing aids made by the use of excluded methods [7 CFR 205.105(e)], prepared with ionizing radiation [7 CFR 205.105(f)], or grown with sewage sludge [7 CFR 205.105(g)].

other than mechanical or biological processes that are primarily intended to make or break covalent chemical bonds are subject to review by the NOSB before being allowed in the processing of organic food products. (Ex. Chemical carbohydrate conversions processes)

- 3) Processes in which nonagricultural substances, other than those allowed in §205.605, are components of the materials and are introduced into the food are subject to review by the NOSB before being allowed in the processing of organic food products. The materials not

~~allowed in §205.605 that are introduced into the food would also need to be petitioned. (Ex. Hydrogenation of oil).~~

- ~~1) Processes in which specific chemical components of the food are selectively and purposely removed during the process via a chemical process vs. a mechanical process are subject to review by the NOSB before being allowed in the processing of organic food products. (Ex. Ion Exchange).~~
- ~~5) Any other process not covered by the above listed guidelines shall be submitted for review. (Ex. UV light)."~~

Commentary

OMRI supports the NOP final rule description of permitted processing techniques at 7CFR 205.270 as "mechanical and biological methods" as being consistent with organic principles and the intent of the OFPA. While the NOSB is not clearly delegated in OFPA with authority to review processes as such, NOSB clearly has authority to review and consider any processes that involve chemical alteration or contact of organic food with substances not included on the National List. These guidelines will help clarify the types of processes that provide an opportunity for such contact. In addition, NOSB may be called upon to review novel or specialized processes to make a determination whether they do involve chemical modification.

By adding the word 'physical' to Guideline (1), this allows physical methods, such as ultraviolet light, to be used without a review. Catalytic reactions that involve ion exchange resins, metal plates for hydrogenation, and caustic finishing and peeling agents would all be considered chemical processing and require a petition for the specific materials used.

Ion Exchange

The NOP Final Rule allows for the limited use of ion exchange. OMRI understands that under the NOP Final Rule, secondary additives that are in direct contact with food are considered processing aids under 7 CFR 205.301(f)(4). The Food and Drug Administration considers ion exchange resins (21 CFR 173.25), ion exchange membranes (21 CFR 173.20), and molecular sieve resins (21 CFR 173.40), to be secondary direct food additives.

Resins used in ion exchange meet the definition of 'processing aid' under the NOP final rule (205.2). The preamble clarifies that the term 'ingredients' as used under the NOP Final Rule includes processing aids and incidental ingredients as well as declared ingredients (65 *Fed. Reg.* 80587). Therefore, ion exchange is not prohibited, but the resins, membranes, or other substances that are in direct food contact and function as processing aids would need to be organically produced or appear on the National List.

OMRI filed this comment with the NOP in response to the second proposed rule

"OMRI considers ion exchange resin columns to be synthetic substances, and therefore prohibited in direct contact with organic food. This is not the same as ionizing radiation and would not be an excluded method. A processor would be able to add allowed non-organic ingredients on the National List prepared or purified by the use of ion exchange—such as water, salt, enzymes, or lecithin—and to a processed food product labeled 'organic' provided all the other ingredients were organically produced or appeared on the National List. However, the use of ion exchange on an organic agricultural product, such as fructose made from organic grapes, would render the resulting ingredient no longer organic." (June 9, 2000).

Ion exchange resins are known to leak from columns and thus become incidental additives in the food. The FDA uses ion exchange resins as an example of consumer exposure to secondary food additives (FDA, 1995). <http://www.cfsan.fda.gov/~dms/opa-cn8e.html>.

Any additive used in direct contact with organic food that functions as an ingredient or processing aid must comply with the requirements of sections 205.270 and 205.301. Water, salt, and organic food can be a media used in ion exchange, as can non-organic ingredients that appear on either sections 7 CFR 205.605 or 7 CFR 205.606 of the National List. Bentonite clay, citric acid, diatomaceous earth, potassium hydroxide, silicon dioxide, and sodium hydroxide are all examples of processing aids used for ion exchange that appear on the National List. Cellulose and gelatin also function as ion exchange agents, and have been the subjects of TAP reviews subsequent to the publication of the NOP Final Rule.

Hydrogenation

Similarly, the hydrogenation of oils would also be considered chemical processing. Unlike nitrogen, oxygen, and carbon dioxide, hydrogen does not appear on the National List. Similarly, the catalysts used to generate hydrogen—such as nickel—also are not on the National List. These are also considered food additives (see 21 CFR 184.1537 for nickel). For hydrogenation to be acceptable, the catalyst would need to appear on the National List.

Carbohydrate conversion

Carbohydrate conversion refers to a number of different techniques for modifying, reducing, or transforming carbohydrates into proteins, fats, or other carbohydrates. Some of these are chemical in nature, some biochemical, some physical, and others biological. Those that are physical are allowed without consideration of additives. Chemical and biochemical modification obviously requires that all of the reactants be either organically produced agricultural ingredients or be on the National List. Biological modification also requires that the organisms used either be organically produced or appear on the National List.

Modified starch would be an example. The acids and bases used for hydrolysis would need to be on the National List. Another example of chemical conversion is carbohydrate reduction involving the use of various charged metal catalysts. If these catalysts are considered food additives, then they must appear on the National List. Yeast fermentation and the conversion of sugar to alcohol are not prohibited because yeast appears on the National List. Enzymatic conversion—such as the use of maltase or amylase to malt grains—is also allowed by the NOP Final Rule without further NOSB review provided that the enzymes are not prepared by excluded methods.

Fermentation and Other Biological Processing

Biological processing is clearly allowed under the NOP Final Rule [205.270(a)]. At present, however, it appears that the NOP rule requires that individual organisms used in biological processing to be either organically produced or appear on the National List. Dairy cultures and yeasts are the only fermentation organisms that currently appear on the National List. There are many others used in organic food processing. These include *Acetobacter* for vinegar, *Leuconostoc* spp. for pickles, *Aspergillus oryzae* (koji) for miso, and *Rhizopus* for tempeh among others. OMRI suggests some options for the NOSB to consider.

- 1) Organisms used as ingredients and processing aids must appear in section 205.605 with an annotation consistent for that application or use. This would require a case-by-case review of such organisms and / or the establishment of organic standards for various microorganisms that are possible to produce as organic agricultural substances.
- 2) The NOSB could request that a TAP review be conducted for the category of all microorganisms used for food processing
- 3) Existing organisms on the National List could be considered models, with similar organisms allowed. That is, dairy cultures could be considered model organisms for bacteria and yeast considered model organisms for fungi. The NOSB could, based on these previous reviews,

propose a technical correction to allow all other non-pathogenic food-grade bacteria, fungi, and other microorganisms ordinarily used to be added to the National List.

- 4) The NOSB could propose the adoption of the following Codex language for either a technical correction or addition to the National List:

"3.4 Preparations of Microorganisms and Enzymes:

Any preparations of microorganisms and enzymes normally used in food processing, with the exception of microorganisms genetically engineered / modified or enzymes derived from genetic engineering."

These may be combined, or a different approach might also be acceptable. However, to clearly allow fermentation or other biological processing of many foods, the NOP Final Rule needs either a technical correction or further additions to the National List.

Additional Commentary

OMRI commented in June 2000 that the NOP Final Rule should be restructured to be more consistent with FDA regulation of food processing. OMRI suggested that the NOP should recognize processing aids as separate from ingredients in a way that is consistent with the FDA's use of those terms (21 CFR §101.100, FDA). While ingredients needed to come from an organic source or be on the National List, processing aids could be from a natural non-organic source without needing to appear on the National List. Synthetic processing aids would, of course, still need to be on the National List. OMRI also suggested a broader allowance for non-organic ingredients and processing aids in the "made with organic" category. NOP did not accept these suggestions, in part because NOSB had not reviewed or endorsed them, and in part because members of organic community objected to the allowance of incidental ingredients and wanted to see processing aids subject to the same requirements as ingredients.

The NOP established a standard that requires all non-organic processing aids, whether natural or synthetic, to be on the National List. A subsequent technical correction proposed by NOSB (June 2001) to correctly identify section 205.605 as including processing aids has not been made at this time, leaving some confusion in the processing community as to whether these items must in fact be added to 205.605 and 205.606. OMRI urges the NOSB to revisit our earlier proposals to clarify the structure of the National List. OMRI believes a separate section should be designated for processing aids, and that section 205.606 is currently very unclear. Some interpret this section as only allowing this closed set of non-organic agricultural ingredients, others believe these five ingredients have been determined to be commercially unavailable in organic form, while another reading holds that these substances must be from organic sources if available and that any non-organic agricultural ingredient may also be used if not commercially available. This confusion will lead to inconsistent certification and enforcement of organic standards if not clarified.

References

Helffferich, F. 1962. *Ion Exchange*. New York: McGraw-Hill. Republished by Dover, 1995.

US Food and Drug Administration. 1995. Estimating Exposure to Direct Food Additives and Chemical Contaminants in the Diet. <http://www.cfsan.fda.gov/~dms/opa-cg8e.html>. Accessed March 11, 2002.



660 PENNSYLVANIA AVE., SE , SUITE 302, WASHINGTON, DC 20003
PHONE (202) 547-9359 FAX (202) 547-9429
WWW.CENTERFORFOODSAFETY.ORG

15 March 2002

National Organic Standards Board
C/O Ms. Katherine Benham
Room 2510 – South Building
14th & Independence Ave., SW
Washington, DC 20250-0001

CC: NOSB.Processing@usda.gov

To the NOSB and NOSB Processing Committee:

The Center for Food Safety (CFS) is pleased to submit the following comments concerning the draft proposal for "Guideline for determining whether a processing technology shall be reviewed by the NOSB." CFS is a non-profit membership organization dedicated to preserving integrity in organic standards. It maintains direct contact with over 100,000 members of the public who have previously commented on proposed USDA organic standards.

At the outset, CFS reiterates its support for the NOSB's legal authority. Under the Organic Food Production Act (OFPA), the National Organic Standards Board (NOSB) is a non-governmental board with a diverse constituency representing organic farmers, environmental organizations, organic marketers, consumers and scientific experts. The NOSB has two distinct roles: (1) to provide the Secretary of Agriculture with recommendations regarding the implementation of the OFPA; and (2) to develop the Proposed National List or amendments to the National List for submission to the Secretary.

The OFPA specifically enumerates the NOSB's legal role in establishing the National List of allowable and prohibitive inputs:

(D) Procedure for establishing National List. (1) In general - The National List established by the Secretary shall be based on a proposed national list or proposed amendments to the National List that is developed by NOSB. (2) No additions. The Secretary may not include exemptions for synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed

Amendments to the National List 7 U.S.C. § 6517(d) (emphasis added).

CFS believes that the NOSB must ensure that guidelines concerning the review of processing technology do not subvert the Board's legal authority to ensure that unapproved synthetic ingredients are not allowed in end product labeled "organic" or "made with organic." Accordingly, CFS provides the following comments.

Consumer Expectation on Synthetics.

During the implementation of the OFPA the USDA has made it clear that the Agency views the organic rule as a marketing standard based upon consumer expectations. This approach has been stated by the Agency's in its treatment of "excluded methods" and irradiation. The USDA has stated:

Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time, consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label. 65 Fed. Reg. 13534-35 (March 13, 2000) (emphasis added).

and

Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of irradiation presents unacceptable risks to the environment or human health and may, in fact, offer certain benefits. Because this rule is a marketing standard and consumers have expressed a clear expectation that irradiation should not be used in the production of organic foods, foods produced with this technology will not be permitted to carry the organic label. 65 Fed. Reg. 13514 (emphasis added).

As a result, the proposed guidelines must clarify and extend these prohibitions to any processing guidelines. Therefore, the NOSB must ensure that by denying review of biological processes that such lack of review does not allow any "biological" processes that use excluded methods or processing aids or techniques that have been produced by excluded method. Similarly, guidelines concerning review of processing techniques such as UV light must be written to ensure that ionizing irradiation is specifically prohibited.

In addition to these clarification, the NOSB Processing Committee must account for the market place expectation of consumers when it comes to the use of synthetic ingredients in products labeled "organic" or "made with organic." As a consumer and environmental organization, the Center for Food Safety represents consumers of organic foods who do not expect to encounter synthetic

ingredients in products labeled “organic” or “made with organic.” This consumer expectation was laid out by Congress in § 6510(a)(1) of the OFPA which states: “For the handling operation certified under this chapter, each person on such handling operation shall not with respect to any agricultural product covered by this chapter (1) add any synthetic ingredient during the processing or any post harvest handling of the product.”

Despite the OFPA’s prohibition, the final rule has allowed synthetic substances as ingredients in/on processes products labeled as “organic” or “made with organic.” 7 C.F.R. § 205.605. Thus, at minimum, consumers may have an expectation that any non-agricultural synthetic substances that are ingredients in products labeled organic or made with organic have been specifically undergone TAP review and been approved for inclusion on the National List by the NOSB. Any processing review guidelines must make sure this market expectation is met.

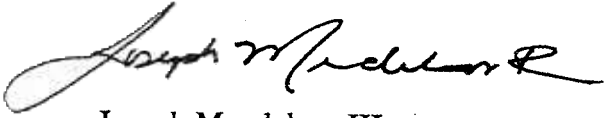
NOSB Authority Concerning Processing Techniques.

At first blush it might appear that the NOSB’s legal authority to review processing techniques is limited to providing recommendations to the Secretary on implementing which processing standards are acceptable. 7 U.S.C. § 6518(a). However, this interpretation ignores a significant part of OFPA’s delegation of authority to the NOSB. The OFPA specifically requires that NOSB will have a role in addressing whether the make up of processed products is allowable under the Act. In exempting any food processing technologies from NOSB review, the Board must ensure it is not reducing or eliminating its legal authority over the content of processed agricultural products.

The National Organic Program final rule defines “ingredient” as “any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.” 7 C.F.R. § 205.2. CFS is aware that many processes such as hydrogenation of oil or ion exchange can result in secondary food additives and/or non-agricultural substances that remain present in the final agricultural product that reaches the consumer. Thus, any processing review guidelines must ensure that should the final product (regardless of processing technique used) contain any non-agricultural synthetic ingredient such product may not be labeled “organic” or made with “organic” unless all synthetics present in that agricultural product have undergone TAP review and been approved by the NOSB for inclusion on the National List. Determinations by the NOSB that such non-agricultural synthetics should not be approved for inclusion on the National List may have the end result of prohibiting the processing techniques that created the presence of that synthetic in the final agricultural product. Such a result is consistent with the OFPA and NOSB’s legal authority. The failure of any processing review guidelines to ensure that NOSB retains this authority over the allowance of synthetics in final a processed agricultural product (for example by exempting from review certain processing techniques that create non-agricultural synthetic ingredients) would be counter to the OFPA and directly contradict the NOSB’s legal authority over the National List process.

Accordingly, CFS recommends that the NOSB clarify its authority concerning this matter and specifically includes language asserting this authority in any guidelines concerning the review of processing technologies.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph Mendelson III". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

Joseph Mendelson III
Legal Director